UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MICHAEL G. HAYEK

Appeal No. 2007-0527
Application No. 09/291,227

ON BRIEF

Before ADAMS, MILLS, and LEBOVITZ, Administrative Patent Judges.

LEBOVITZ, Administrative Patent Judge.

DECISION ON APPEAL

This appeal involves claims to feeding a dog or cat lutein to enhance its immune response. The Examiner has rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 134. We affirm.

The claims

Claims 1 and 3-8, which are all the pending claims in the instant application, are on appeal. Br. 2. There are two prior art rejections under 35 U.S.C. § 103(a), each covering claims 1 and 3-8. Appellant did not provide separate reasons for

patentability for any individual claim within each grouping. Consequently, we select claim 1 as representative for deciding each ground of rejection. 37 C.F.R. § 41.37(c)(1)(vii).

> 1. A process for enhancing immune response of a companion animal consisting of a dog or cat, said process comprising the step of feeding said animal in need of such treatment a diet containing an effective immune enhancing amount of lutein, wherein the diet contains from about 1 to about 50 mg/day of lutein for a time sufficient for said lutein to be absorbed by said animal.

Evidence relied upon

The Examiner relies on the following prior art references to establish unpatentability of the claimed subject matter:

Ito et al. (Ito) U.S. Pat. 5,937,790 Aug. 17, 1999

Jyonouchi et al. (Jyonouchi), "Immunomodulating actions of carotenoids: Enhancement of in vivo and in vitro antibody production to T-dependent antigens," *Nutrition and Cancer*, 21, pp. 47-58 (1994)

Krinsky, "Effects of carotenoids in cellular and animal systems," *American Journal of Clinical Nutrition*, 53, pp. 238s-246s (1991).

Health 2000 (was cited as "Anon" in the final rejection), "Ailment specific dietary supplements," *New Product News*, 32, No. 12, p. 40 (1997).

Michael J. Derelanko & Mannfred A. Hollinger eds., *CRC Handbook of Toxicology*, p. 11 (1991).

Obviousness under 35 U.S.C. § 103(a)

1. Claims 1 and 3-8 stand rejected under 35 U.S.C. § 103(a) as obvious over Ito.

Ito describes "a method of reducing stress in animals, which comprises simultaneously administering . . . one or more substances selected from the group consisting of L-ascorbic acid-2-phosphoric acid, a salt thereof and an L-ascorbic acid-2-glucoside, as an active ingredient, and 0.02 g/kg-body weight or more of another antioxidant substance." Col. 5, ll. 38-45. The anti-oxidant substance can be "selected from the group consisting of carotene, astaxanthin, lutein, dl-α-tocopheryl acetate, α-tocopherol, SOD, glutathione and catechins." Col. 5, ll. 18-21. Table 1 describes an example of an anti-stress agent composition which contains a mixture of anti-oxidants, including "lutein-blended Marry Gold extract." Col. 8, ll. 20-26. "The anti-stress agent for animals of the present invention can prevent the stress reaction of animals and inhibit various disorders accompanying the stress, such as a loss in body weight and a reduction in immunity." Col. 1, ll. 23-26.

The Examiner asserts that "it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ lutein as the antioxidants in Ito's method since Lutein is one of the eight disclosed species (column 5, line 17-20), and is one of the preferred species (table 1 in column 8)." Answer 4: 8-11. "Further[,] the reduction of stress certainly enhance[s] the immunity since stress is known to reduce the immunity." *Id.*, 4: 13-14. "As to the amounts of lutein specified herein 1-50 mg/day, note a dog or cat feed 5 to 250 grams/day of the feed disclosed by Ito (contains 0.2% of antioxidants) would meet this limitation." *Id.*, 4: 14-16.

Appellant argues that anti-oxidants are added to the anti-stress agents in order "to prevent or inhibit oxidation of the active [,] thereby enhancing the efficacy of the L-ascorbic acid-2-phosphoric acid or L-ascorbic acid 2-glucoside as anti-stress agents." Br. 4:15-17. He asserts that Ito does not attribute any anti-

stress or immune function to the anti-oxidant agents. *Id.*, 4:27 to 5:4. Appellant also contends that "the disclosure of Ito only relates to animals which are stressed." *Id.*, 5: 18. "Ito fails to describe or even suggest treatment of healthy, unstressed animals. *Id.*, 6: 11-12. Finally, he asserts that Ito does not describe "enhancement of immunity in a cat or dog" as required by the claims. *Id.*, 6: ll. 5-6 and 20-22.

We agree with the Examiner that Ito teaches a method which would enhance the immune response of animals (including dogs and cats) comprising feeding the animals a composition which contains lutein, as required by claim 1. "Test segment 5" (Ito, col. 8, ll. 20-26) shows a feed composition that contains lutein as a component. This feed composition is described to inhibit the reduction in immunity associated with stress (col. 1, ll. 23-26) which the Examiner correctly understands to enhance the immunity of the stressed animals in accordance with claim 1.

Even assuming that Ito only teaches feeding its lutein composition to stressed animals as asserted by Appellant (Br. 5 to 6), we do not find that this undermines the rejection because the claims are not limited to healthy animals. The treatment of stressed animals would meet the claimed requirement of feeding a lutein to an "animal in need of such treatment."

Appellant argues that Ito does not teach that the immunity of a dog or cat is enhanced. We do not agree. Ito states that its composition can inhibit a "reduction in immunity" associated with stress. Col. 1, ll. 23-26. Stressed animals fed the composition (L-ascorbic acid and lutein at col. 8, ll. 20-26) would show an increase or enhancement of immunity as compared to animals fed a control composition (without L-ascorbic acid and lutein). Thus, we agree with the Examiner that an "inhibition of reduction in immunity" as described in Ito is

equivalent to "enhancing [an] immune response" in an "animal in need of such treatment" as required by claim 1.

Appellant asserts that "the Examiner is assuming that alteration of measured stress protein results in changes in immune response, however, this is not demonstrated by Ito." Br. 6: 7-8. This argument is not persuasive. Ito states that immunity reduction accompanies stress. Col. 1, ll. 23-26; col. 14, ll. 45-47. Thus, the Examiner is not making an assumption, but rather is relying on Ito's express statement of the association of stress and immune inhibition. Appellant has not produced any evidence that Ito's statement is wrong or would have been disbelieved by the person of ordinary skill at the time the invention was made. Arguments of counsel cannot take the place of evidence lacking in the record. *Estee Lauder Inc. v. L'Oreal, S.A.*, 129 F.3d 588, 595, 44 USPQ2d 1610, 1615 (Fed. Cir. 1997).

We are also not persuaded by Appellant's argument that the rejection is flawed because Ito did not recognize that lutein had an immune-enhancing effect as required by claim 1. Br. 4 to 5. Appellant does not challenge the Examiner's finding (Answer 4: 1) that Ito teaches an amount of lutein that would meet the claimed limitation of "from about 1 to about 50 mg/day" of lutein. It is true that Ito did not state that this amount of lutein, alone, is "immune enhancing" as required by claim 1, but it does teach administering a composition containing a quantity of lutein for a purpose which would encompass the claimed process of enhancing the immune response. Merely because Appellant has described another advantage to lutein administration, in addition to its anti-oxidant properties, does not impart patentability when Ito clearly suggests what Appellant has done. *In re Kronig*, 539 F.2d 1300, 1304, 190 USPQ 425, 428 (CCPA 1976). *See also In re Baxter Travenol Labs.*, 952 F.2d 388, 392, 21 USPQ2d 1281, 1285 (Fed. Cir.

1991) ("Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention."); *Ex parte Obiaya*, 227 USPQ 58, 60 (B.P.A.I. 1985)("The fact that appellant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious.").

For the foregoing reasons, we find that the Examiner has provided sufficient evidence to establish a case of prima facie obviousness for claim 1. Because Appellant has not provided persuasive arguments to rebut it, we affirm the rejection of claim 1. Claims 3-8 fall with claim 1 because separate reasons for their patentability were not provided.

2. Claims 1 and 3-8 stand rejected under 35 U.S.C. § 103(a) as obvious over Ito in view of Jyonouchi, Anon, Krinsky, and CRC Handbook of Toxicology.

Ito has already been described above. The Examiner states that Jyonouchi teaches that carotenoids, including lutein, are known to be useful in enhancing the immune response. Answer 5. Krinsky is cited for disclosing that it is well known that carotenoids enhance the immune response. *Id.* Based on these teachings, the Examiner concludes that "[a] person of ordinary skill in the art would have been motivated to employ Ito's feed with lutein as the antioxidant, to feed [a] cat or dog for enhancing their immune systems because lutein is known to be useful for enhancing the immune system of animals." Answer 6: 1-4.

Appellant argues that Jyonouchi describes intraperitoneal administration of lutein to mice, but "fails to teach or suggest oral administration of lutein in any animal for any purpose." Br. 7. He asserts that "one of ordinary skill in the art would have failed to infer from the combination of references that lutein would be absorbed at effective levels following oral administration so as to have the claimed effect on the immune system." Br. 8: ll. 4-7. He provides a declaration to support

this position. Appellant also argues that "from about 1 to about 50 mg/day of lutein in the diet in order to effect the recited functional response . . . is not taught or even suggested in either Ito or Jyonouchi." *Id.*, 8.

In order to establish a case of prima facie obviousness, it must be shown that all elements of a claimed invention are found in a combination of prior art references and that the person of ordinary skill in the art would have been motivated with a reasonable expectation of success to have made the claimed composition or device, or carry out the claimed process. *See Velander v. Garner*, 348 F.3d 1359, 1363, 68 USPQ.2d 1769, 1772 (Fed. Cir. 2003). On the record before us, we find that there is sufficient evidence to establish that a person of ordinary skill in the art would have been motivated (Answer 6: 1-4) with a reasonable expectation of success (Answer: 5, particularly Anon and Jyonouchi) to have employed lutein in Ito's feed for its known immune enhancing properties. Thus, for the reasons articulated by the Examiner, we affirm this rejection.

We do not agree with Appellant that Jyonouchi does not suggest oral administration of lutein "in any animal for any purpose." Br. 7. In the abstract, Jyonouchi asserts that its results "suggest that carotenoid supplementation may be beneficial in restoring humoral immune responses in older animals." Jyonouchi, p. 47. It is also stated that "[i]t may thus be speculated that dietary carotenoids can help restore specific Ab responses in older humans." *Id.*, p. 56. Lutein is characterized by Jyonouchi as a carotenoid. *Id.*, p. 48, l. 14; p. 50, ll. 31-32; p. 55. Thus, Jyonouchi clearly do suggest feeding (i.e., "dietary") lutein to animals to enhance the immune response, as required by claim 1.

Inventor Hayek asserts in a declaration under 37 C.F.R. § 1.132 that the "skilled artisan could not have reasonably inferred from the Jyonouchi reference that lutein would be absorbed at effective levels follow oral administration to have

the claimed affect [sic] on the immune system and immune response in companion animals." Dec. ¶ 5.

"While objective factual evidence going towards a § 103 determination is preferable to statements of opinion on the issue, the nature of the matter sought to be established, as well as the strength of the opposing evidence, must be taken into consideration in assessing the probative value of expert opinion." *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 294, 227 USPQ 657, 665 (Fed. Cir. 1985), cert. denied, 475 U.S. 1017 (1986). In this case, we find that there is stronger evidence of record which is contrary to Dr. Hayek's opinion.

First, as discussed above, Jyonouchi suggests (p. 56) dietary lutein to enhance the immune response, implying that the skilled worker would have reasonably believed that effective amounts of lutein would be absorbed when part of an animal's diet. Secondly, the Examiner provides factual evidence that lutein would have been expected to be effective when ingested orally. This includes the Ito patent, which teaches an animal feed that comprises lutein (col. 8, ll. 20-26), and Anon, which teaches a dietary supplement that contains lutein (p. 40, "Eyes with Lutein"). *See* Answer 7: ¶ 11. Finally, Appellant admits in the *Background* section of their application that "[d]ietary lutein was . . . found to enhance lymphocyte proliferation in mouse splenocytes." Specification 1: 24-25. Based on the totality of evidence, including Appellant's own admission, we agree with the Examiner that the skilled worker would have reasonably believed that lutein would be orally absorbed in effective amounts.

Appellant also argues that the claimed requirement that "from about 1 to about 50 mg/day" of lutein is fed to animals is not met by the prior art. Br. 8. We disagree. The Examiner cited Ito for its teaching of an antioxidant concentration

that would meet this claim limitation. Answer 6: 4-6. Appellant does not identify a specific defect in the Examiner's reasoning, and we find none.[1]

For the foregoing reasons, we affirm the rejection of claim 1. Because separate reasons for patentability were not provided, claims 3-8 fall with claim 1.

TIME PERIOD

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

DONALD E. ADAMS)
Administrative Patent Judge)
)
DEMETRA J. MILLS) BOARD OF PATENT
Administrative Patent Judge)
) APPEALS AND
) INTERFERENCES
RICHARD M. LEBOVITZ)
Administrative Patent Judge)

[1] The Examiner states that Ito discloses a feed comprising "0.02% antioxidants." Answer 5: 2. For clarification, we note the following: Ito at col. 5, ll. 65-66 states that "200 ppm [parts per million] or more of an antioxidant substance" is present in the feed composition. This value is equal to 200/1,000,000 or 0.02% of the feed composition. On a per kilogram of feed basis, this would be 0.02 gm/100 kg or 0.2 gm/1000 gm or 200 mg/kg. According to the instant application, "from about 1 to about 50 mg/day of lutein" is equal to "from about 2 to about 315 mg lutein/kg diet. Specification 1: 9-10. Thus, Ito discloses an amount of lutein which falls within the claimed range. Appellant does not identify any deficiency in the Examiner's statement about the concentration of antioxidant described in Ito.

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